

1
Cont clinical score, disease incidence and leukocytosis following *Streptococcus equi* challenge as compared to non-vaccinated horses.

REMARKS

Claims 1-21 are under consideration in this application. Claims 1, 2, 5, 10, 15, 17 and 19-21 stand rejected under 35 U.S.C. 102(b). Claims 1, 3, 10, 17, and 19-21 stand rejected under 35 U.S.C. 102(a). Claims 1-21 stand rejected under 35 U.S.C. 103(a). Claim 1 is amended.

Reconsideration of this application is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102(b)

The Examiner maintains his rejection of claims 1, 2, 5, 10, 15, 17 and 19-21 under 35 U.S.C. 102(b) as being anticipated by either Timoney (U.S. Patent No. 5,183,659) ("659 patent") or Timoney (PCT WO 87/00436) ("436 PCT"). The Examiner contends that the claimed invention does not recite an immunostimulant to be administered in addition to live attenuated virus. Applicant respectfully traverses the rejection.

During a May 25, 1999 telephone call between the undersigned and the Examiner, the fact that the M protein of the Timoney references is part of the *S. equi* bacterial strain 709-27 and is not an additional immunostimulant added to enhance the immunogenicity of the vaccine as claimed was discussed. The Examiner suggested adding language from the Specification at page 3, line 27 to replace "and" with "in combination with." As suggested by

the Examiner, claim 1 has been amended to read as "A composition comprising a live attenuated *Streptococcus equi* in combination with an immunostimulant..."

In light of the foregoing remarks and amendment, applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. 102(b). In addition, since claims 2, 5, 10, 15, 17 and 19-21 contain all of the limitations, features and attributes of claim 1, these claims are also not anticipated over the cited art. In re Fine, 5 U.S.P.Q. 2d 1596, 1600 (Fed. Cir. 1988).

REJECTIONS UNDER 35 U.S.C. § 102(a)

The Examiner maintains his rejection of claims 1, 3, 10, 17 and 19-21 under 35 U.S.C. 102(a) as being anticipated by Hartford et al (European Patent Application No. EP 0 786 518 A1) ("Hartford"). Applicant respectfully traverses the rejection.

The Examiner argues that claim 1 as amended in the previous March 22, 1999 response "is drawn to an intended use, i.e. use of claimed composition for vaccination of horses..." During the above-mentioned May 25, 1999 telephone conversation with the Examiner, the undersigned explained that the requirement for the composition to both elicit protective immunity and demonstrate significant differences in the parameters measured following challenge are specific properties of the composition and not parameters of intended use. The Examiner suggested that claim 1 be amended to reflect the fact that the composition as claimed possesses the property of eliciting protective immunity. Claim 1 has thus been amended to read as a "composition having the property of eliciting protective immunity from

Streptococcus equi infection, such that vaccinated horses demonstrate significant differences in mortality, total clinical score, disease incidence and leukocytosis following *Streptococcus equi* challenge as compared to non-vaccinated horses."

Hartford teaches a new mutated *Streptococcus equi* strain TW 928, which comprises a large deletion (about 1 kb) in its genome. Hartford nowhere exemplifies the use of adjuvant (*i.e.* an immunostimulant) in combination with its mutated strain. In addition, Hartford does not teach a composition comprising the *Streptococcus equi* strain in combination with an immunostimulant that has the property of eliciting protective immunity in horses. Not only is there no exemplification of a combination with an immunostimulant, but, with regard to the challenge and testing of an efficacious vaccine, Hartford solely discloses administration of its *Streptococcus equi* strain to BALB/c mice. The only tests in horses were carried out to determine the safety of the attenuated virus. No vaccination and challenge with live virus was ever carried out in horses. See Example V at page 12. Hartford provides no teaching of its vaccine's possession of the property of eliciting protective immunity in horses as claimed. The cited reference does not disclose the limitations of the recited claims.

In light of the foregoing, applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. 102(a). In addition, since claims 3, 10, 17 and 19-21 contain all of the limitations, features and attributes of claim 1, these claims are not anticipated by the cited art. In re Fine, 5 U.S.P.Q. 2d 1596, 1600 (Fed. Cir. 1988).

REJECTIONS UNDER 35 U.S.C. § 103(a)

The Examiner maintains his rejection of claims 1-21 under 35 U.S.C. 103(a) over Timoney or Timoney in view of Hartford and Gerber (U.S. Patent No. 4,806,350) ("Gerber"). The Examiner argues that applicant's arguments put forth in the March 25, 1999 response are not persuasive because claim 1 is drawn to an intended use and does not recite a separate immunostimulant. Applicant respectfully traverses the rejection.

In light of the May 25, 1999 telephone conversation between the Examiner and the undersigned, as well as the remarks and amendments put forth and discussed above, applicant respectfully submits that: 1) claim 1 as amended is not drawn to an intended use, but rather recites a composition having a specific and well defined property, namely, that of eliciting protective immunity from *Streptococcus equi* infection, such that vaccinated horses demonstrate significant differences in mortality, total clinical score, disease incidence and leukocytosis following *Streptococcus equi* challenge as compared to non-vaccinated horses; and that 2) claim 1 as amended does recite a separate immunostimulant, namely, a composition comprising a live attenuated *Streptococcus equi* in combination with an immunostimulant. Claim 1 as amended is thus directed to a live attenuated *Streptococcus equi* in combination with an immunostimulant having the property of eliciting protective immunity, and claims 2-21 incorporate all of the limitations of claim 1.

As discussed above, neither the Timoney nor the Hartford references apply to the invention as claimed. The Timoney M protein is "retained on" the *Streptococcus equi*, i.e., the M protein is part of the *S. equi* bacterium and is not a separate immunostimulant.

The Timoney references do not suggest or motivate the reader to incorporate an immunostimulant in combination with the live *Streptococcus equi*. The Hartford reference does not suggest the claimed property of eliciting protective immunity in a horse. A person of ordinary skill in the art would not expect to enhance the protective immunity of a live vaccine in an animal if that vaccine had not been shown to be protective that animal. Indeed, no one reading the mouse study of Hartford would have a reasonable expectation that administration of the Hartford vaccines would provide protective immunity in horses, let alone demonstrate significant differences in mortality, total clinical score, disease incidence and leukocytosis following *Streptococcus equi* challenge as compared to non-vaccinated horses.

With regard to Gerber, while the reference does teach the use of saponin as an adjuvant, nowhere does it motivate the reader to use it as an immunostimulant in combination with a the *Streptococcus equi* for stimulating mucosal immunity as claimed herein. Gerber nowhere makes up for the deficiencies of Timoney and Hartford.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. 103(a). In addition, since claims 2-21 each contain all of the limitations, features and attributes of claim 1, these claims should also be found non-obvious over the cited art. In re Fine, 5 U.S.P.Q. 2d 1596, 1600 (Fed. Cir. 1988).

CONCLUSION

In light of the foregoing, reconsideration and withdrawal of all of the objections and rejections are respectfully requested. Applicant submits that all of claims 1-21 are in condition for allowance. Prompt and favorable allowance of the claims is requested. If for any reason the Examiner concludes that any of the claims as amended is not properly allowable, the Examiner is respectfully requested to contact the undersigned by telephone at 212-527-7679.

Respectfully submitted,



Anne E. Zitron, Ph.D.

Reg. No. 41,391

Agent for Applicant

DARBY & DARBY P.C.
805 Third Avenue, 27th Floor
New York, New York 10022
(212) 527-7700

M:\0532\0B169\AEZ0051.W3P

Amendment
Serial No.: 09/007,385